

# Kengo Nagashima

PROJECT ASSOCIATE PROFESSOR · BIOSTATISTICIAN

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## Research Interests

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**Biostatistics & Statistical Methodology:** My research interests are Survival Analysis, Meta-analysis, Causal Inference, Bayesian Inference, and Diagnostic Statistics. I am also interested in Biomarkers in Clinical Trials, Cancer Clinical Trials, Adaptive Designs, Model Selection, Model Misspecification, Categorical Data Analysis, Exact Methods, Statistical Softwares, Missing Data, Semiparametric Models, Estimating Equations, Inference for High-dimensional Data, Statistical Machine Learning, Genetic Epidemiology, Population Pharmacokinetics, and Quasi-Monte Carlo Integration.

## Professional Positions

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### Biostatistics Unit, Clinical and Translational Research Center, Keio University Hospital

PROJECT ASSOCIATE PROFESSOR

*Tokyo, Japan*

*April 2021–present*

### Research Center for Medical and Health Data Science, The Institute of Statistical Mathematics

PROJECT ASSOCIATE PROFESSOR

*Tokyo, Japan*

*April 2018–March 2021*

### Department of Global Clinical Research, Graduate School of Medicine, Chiba University

RESEARCH ASSISTANT PROFESSOR

*Chiba, Japan*

*April 2015–March 2018*

### Clinical Research Center, Chiba University Hospital

RESEARCH ASSISTANT PROFESSOR

*Chiba, Japan*

*April 2013–March 2015*

### Faculty of Pharmaceutical Sciences, Josai University

RESEARCH ASSOCIATE

*Saitama, Japan*

*April 2008–March 2013*

## PART-TIME / VISITING POSITIONS

### Akita University Graduate School of Medicine

LECTURER (PART-TIME)

*Akita, Japan*

*April 2024–present*

### Division of Cancer Therapeutics, National Cancer Center Research Institute

VISITING SCIENTIST

*Tokyo, Japan*

*July 2023–present*

### Faculty of Medicine, Nippon Medical School

LECTURER (PART-TIME)

*Tokyo, Japan*

*April 2021–present*

### Graduate School of Engineering, Tokyo University of Science

LECTURER (PART-TIME)

*Tokyo, Japan*

*April 2016–present*

## Department of Translational Oncology, National Cancer Center Research Institute

VISITING SCIENTIST

Tokyo, Japan

November 2021–October 2022

## Research Center for Medical and Health Data Science, The Institute of Statistical Mathematics

VISITING ASSOCIATE PROFESSOR

Tokyo, Japan

April 2021–March 2023

## Department of Biomarkers for the Early Detection of Cancer, National Cancer Center Research Institute

VISITING SCIENTIST

Tokyo, Japan

September 2019–August 2021

## Keio University School of Medicine

LECTURER (PART-TIME)

Tokyo, Japan

April 2019–March 2021

## Keio University School of Medicine

VISITING ASSOCIATE PROFESSOR

Tokyo, Japan

November 2018–March 2021

## Education

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### Tokyo University of Science

PH.D. IN ENGINEERING

Tokyo, Japan

April 2010–March 2014

Dissertation: “Statistical screening methods for pharmacokinetics-related genes in genome-wide studies”

### Tokyo University of Science

M.SC. IN ENGINEERING

Tokyo, Japan

April 2006–March 2008

Master’s Thesis: “A comparison of statistical methods for SNP association analysis under Hardy–Weinberg disequilibrium”

### Tokyo University of Science

B.SC. IN ENGINEERING

Tokyo, Japan

April 2002–March 2006

## Publications (Peer-Reviewed)

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### STATISTICAL METHODOLOGY AND APPLICATIONS IN BIOSTATISTICS

- 1 Goshu M, Ryota Ishii R, Nagashima K, Noma H, Maruo K. Determining the prior mean in Bayesian logistic regression with sparse data: A non-arbitrary approach. *Journal of the Royal Statistical Society: Series C (Applied Statistics)* 2025; **74**(1): 126–141. DOI: [10.1093/jrssc/qlae048](https://doi.org/10.1093/jrssc/qlae048).
- 2 Kimura R, Nomura S, Nagashima K, Sato Y. Comparison between asymptotic and re-randomisation tests under non-proportional hazards in a randomised controlled trial using the minimisation method. *BMC Medical Research Methodology* 2024; **24**(1): 166. DOI: [10.1186/s12874-024-02295-2](https://doi.org/10.1186/s12874-024-02295-2).
- 3 Goshu M, Ohigashi T, Nagashima K, Ito Y, Maruo K. Bias in odds ratios from logistic regression methods with sparse data set. *Journal of Epidemiology* 2023; **33**(6): 265–275. DOI: [10.2188/jea.JE20210089](https://doi.org/10.2188/jea.JE20210089).
- 4 Noma H, Nagashima K, Kato S, Teramukai S, Furukawa TA. Flexible random-effects distribution models for meta-analysis. *Journal of Epidemiology* 2022; **32**(10): 441–448. DOI: [10.2188/jea.JE20200376](https://doi.org/10.2188/jea.JE20200376). arXiv: [2003.04598](https://arxiv.org/abs/2003.04598).
- 5 Hamaguchi Y, Noma H, Nagashima K, Yamada T, Furukawa TA. Frequentist performances of Bayesian prediction intervals for random-effects meta-analysis. *Biometrical Journal* 2021; **63**(2): 394–405. DOI: [10.1002/bimj.201900351](https://doi.org/10.1002/bimj.201900351). arXiv: [1907.00345](https://arxiv.org/abs/1907.00345).

- 6 Nagashima K, Noma H, Sato Y, Goshu M. Sample size calculations for single-arm survival studies using transformations of the Kaplan–Meier estimator. *Pharmaceutical Statistics* 2021; **20**(3): 499–511. DOI: [10.1002/pst.2090](https://doi.org/10.1002/pst.2090). arXiv: [2012.03355](https://arxiv.org/abs/2012.03355).
- 7 Noma H, Nagashima K, Furukawa TA. Permutation inference methods for multivariate meta-analysis. *Biometrics* 2020; **76**(1): 337–347. DOI: [10.1111/biom.13134](https://doi.org/10.1111/biom.13134). arXiv: [1809.03935](https://arxiv.org/abs/1809.03935).
- 8 Nagashima K, Noma H, Furukawa TA. Prediction intervals for random-effects meta-analysis: a confidence distribution approach. *Statistical Methods in Medical Research* 2019; **28**(6): 1689–1702. DOI: [10.1177/0962280218773520](https://doi.org/10.1177/0962280218773520). arXiv: [1804.01054](https://arxiv.org/abs/1804.01054).
- 9 Noma H, Nagashima K, Maruo K, Goshu M, Furukawa TA. Bartlett-type corrections and bootstrap adjustments of likelihood-based inference methods for network meta-analysis. *Statistics in Medicine* 2018; **37**(7): 1178–1190. DOI: [10.1002/sim.7578](https://doi.org/10.1002/sim.7578).
- 10 Goshu M, Sato Y, Nagashima K, Takahashi S. Trends in study design and the statistical methods employed in a leading general medicine journal. *Journal of Clinical Pharmacy and Therapeutics* 2018; **43**(1): 36–44. DOI: [10.1111/jcpt.12605](https://doi.org/10.1111/jcpt.12605).
- 11 Nagashima K, Sato Y. Information criteria for Firth’s penalized partial likelihood approach in Cox regression models. *Statistics in Medicine* 2017; **36**(21): 3422–3436. DOI: [10.1002/sim.7368](https://doi.org/10.1002/sim.7368). [Postprint].
- 12 Sato Y, Goshu M, Nagashima K, Takahashi S, Ware JH, Laird NM. Statistical methods in the *Journal* — an update. *New England Journal of Medicine* 2017; **376**(11):1086–1087. DOI: [10.1056/NEJMc1616211](https://doi.org/10.1056/NEJMc1616211). (Correspondence)
- 13 Noma H, Nagashima K. A note on the Mantel–Haenszel estimators when the common effect assumptions are violated. *Epidemiologic Methods* 2016; **5**(1): 19–35. DOI: [10.1515/em-2015-0004](https://doi.org/10.1515/em-2015-0004).
- 14 Nagashima K, Sato Y, Noma H, Hamada C. An efficient and robust method for analyzing population pharmacokinetic data in genome-wide pharmacogenomic studies: a generalized estimating equation approach. *Statistics in Medicine* 2013; **32**(27): 4838–4858. DOI: [10.1002/sim.5895](https://doi.org/10.1002/sim.5895). arXiv: [1805.05017](https://arxiv.org/abs/1805.05017).
- 15 Goshu M, Nagashima K, Sato Y. Study designs and statistical analyses for biomarker research. *Sensors* 2012; **12**(7): 8966–8986. DOI: [10.3390/s120708966](https://doi.org/10.3390/s120708966). (Review)
- 16 Nagashima K, Sato Y, Hamada C. A modified maximum contrast method for unequal sample sizes in pharmacogenomic studies. *Statistical Applications in Genetics and Molecular Biology* 2011; **10**(1): Article 41. DOI: [10.2202/1544-6115.1560](https://doi.org/10.2202/1544-6115.1560). arXiv: [2012.03475](https://arxiv.org/abs/2012.03475).
- 17 Sato Y, Laird NM, Nagashima K, Kato R, Hamano T, Yafune A, Kaniwa N, Saito Y, Sugiyama E, Kim S-R, Furuse J, Ishii H, Ueno H, Okusaka T, Saijo N, Sawada J-i, Yoshida T. A new statistical screening approach for finding pharmacokinetics-related genes in genome-wide studies. *The Pharmacogenomics Journal* 2009; **9**(2): 137–146. DOI: [10.1038/tpj.2008.17](https://doi.org/10.1038/tpj.2008.17).

## MEDICAL RESEARCHES

- 18 Baba K, Suzuki N, Imamura CK, Booka E, Takahari D, Kawakami T, Kawakubo H, Kitagawa C, Kono Y, Ogura K, Kito Y, Saito K, Yamamoto S, Takeuchi H, Kudo T, Tsunoda T, Mizukami T, Yamaguchi T, Shoji H, Saito K, Tanoue K, Baba E, Nagashima K, Boku N. A phase I/II trial evaluating the safety of increased-dose S-1 with oxaliplatin and nivolumab in HER2-negative advanced gastric cancer. *BMC Cancer* 2025; **25**: 675. [10.1186/s12885-025-14084-1](https://doi.org/10.1186/s12885-025-14084-1).
- 19 Sado M, Nagashima K, Koreki A. Scoring system for the Japanese version of the ICECAP-A. *Psychology Research and Behavior Management* 2025; **18**: 703–717. DOI: [10.2147/PRBM.S480328](https://doi.org/10.2147/PRBM.S480328).
- 20 Hoshino K, Iwasawa S, Yoshioka N, Suzuki S, Hashimoto I, Ukita S, Toshima G, Nagashima K, Takebayashi T, Tsunoda M. Increased risk of proximal tubular dysfunction due to occupational cadmium exposure: a survival analysis study. *Journal of Occupational Health* 2025; **67**(1): uiaf016. DOI: [10.1093/joccuu/uiaf016](https://doi.org/10.1093/joccuu/uiaf016).

- Okui J\*, Nagashima K\*, Matsuda S\*, Sato Y, Kawakubo H, Takeuchi M, Hirata K, Yamamoto S, Nomura M, Tsushima T, Takeuchi H, Kato K, Kitagawa Y. Investigating the synergistic effects of immunochemotherapy in esophageal squamous cell carcinoma. *Esophagus* 2025; **22**(2): 188–197. DOI: [10.1007/s10388-025-01113-y](https://doi.org/10.1007/s10388-025-01113-y). (\*equally contributed)
- Ishibashi R, Takatsuna Y, Koshizaka M, Tatsumi T, Takahashi S, Nagashima K, Ishikawa K, Kaiho T, Asaumi N, Baba T, Yamamoto S, Yokote K, The COMET Trial investigators. Ranibizumab with luseogliflozin in type 2 diabetes with diabetic macular oedema: a randomised clinical trial. *Diabetes, Obesity and Metabolism* 2025; **27**(5): 2473–2484. DOI: [10.1111/dom.16244](https://doi.org/10.1111/dom.16244).
- Hirano H, Takahashi N, Amanuma Y, Suzuki N, Takahari D, Kawakami T, Kudo-Saito C, Nagashima K, Boku N, Kato K, Shoji H. Phase II trial of nab-paclitaxel plus ramucirumab in combination with nivolumab for unresectable advanced or recurrent gastric cancer after progression on first-line treatment including fluoropyrimidine, platinum, and anti-PD-1/PD-L1 antibody (PADDLE). *BMC Cancer* 2025; **25**(1): 201. DOI: [10.1186/s12885-025-13591-5](https://doi.org/10.1186/s12885-025-13591-5).
- Yamada Y, Seto Y, Yoshikawa T, Takeuchi H, Kitagawa Y, Kodera Y, Doki Y, Yoshida K, Muro K, Kabeya Y, Kamada A, Nagashima K, Kumamaru H, Tachimori H, Sasako M, Katai H, Konno H, Kakeji Y. Postoperative adjuvant chemotherapy in patients with gastric cancer based on the Nationwide Gastric Cancer Registry in Japan. *Global Health & Medicine* 2025; **7**(1): 13–27. DOI: [10.35772/ghm.2024.01080](https://doi.org/10.35772/ghm.2024.01080).
- Watanabe T, Oka H, Nagashima K, Nishi H, Kumai Y, Iijima H, Okami K, Shimizu Y, Kano S, Ito K, Yamazaki T, Takahashi H, Oridate N, Yokota T, Koyama T, Kiyota N, Sato Y, Takahashi S, Kato K, Kadowaki S, Honma Y. Clinical outcomes of recurrent or metastatic head and neck cancer after failure of platinum and nivolumab: a multicenter retrospective study. *The Oncologist* 2025; **30**(3): oyaf018. DOI: [10.1093/oncolo/oyaf018](https://doi.org/10.1093/oncolo/oyaf018).
- Ishida N, Harada S, Toki R, Hirata A, Matsumoto M, Miyagawa N, Iida M, Edagawa S, Miyake A, Kuwabara K, Shibuki T, Kato S, Arakawa K, Kinoshita K, Sakurai-Yageta M, Tamiya G, Nagashima K, Muraoka H, Sato Y, Takebayashi T. Causal relationship between body mass index and insulin resistance: linear and nonlinear Mendelian randomization study in a Japanese population. *Journal of Diabetes Investigation* 2025. In press. DOI: [10.1111/jdi.14377](https://doi.org/10.1111/jdi.14377).
- Yamaguchi R\*, Oda T\*, Nagashima K. Comparison of the diagnostic accuracy of shear wave elastography with transient elastography in adult nonalcoholic fatty liver disease: a systematic review and network meta-analysis of diagnostic test accuracy. *Abdominal Radiology* 2025; **50**(2): 734–746. DOI: [10.1007/s00261-024-04546-8](https://doi.org/10.1007/s00261-024-04546-8). (\*equally contributed)
- Inoue M, Ogasawara S, Kobayashi K, Okubo T, Itokawa N, Obu M, Fujimoto K, Unozawa H, Yumita S, Fujiwara K, Nakagawa M, Kanzaki H, Koroki K, Kiyono S, Nakamura M, Kanogawa N, Kondo T, Nakamoto S, Nagashima K, Itobayashi E, Atsukawa M, Koma Y, Azemoto R, Kato N. Assessment of macrovascular invasion in advanced hepatocellular carcinoma: clinical implications and treatment outcomes with systemic therapy. *Liver Cancer* 2025; **14**(1): 8–18. DOI: [10.1159/000539380](https://doi.org/10.1159/000539380).
- Shoji H, Kudo-Saito C, Nagashima K, Imazeki H, Tsugaru K, Takahashi N, Kawakami T, Amanuma Y, Wakatsuki T, Okano N, Narita Y, Yamamoto Y, Rika Kizawa R, Muro K, Aoki K, Boku N. Myeloid subsets impede the efficacy of anti-PD1 therapy in patients with advanced gastric cancer (WJOG10417GTR study). *Journal for ImmunoTherapy of Cancer* 2024; **12**(11): e010174. DOI: [10.1136/jitc-2024-010174](https://doi.org/10.1136/jitc-2024-010174).
- Matsuyama E, Miyata J, Terai H, Miyazaki N, Iwasaki T, Nagashima K, Watase M, Sunata K, Namkoong H, Asakura T, Masaki K, Chubachi S, Ohgino K, Kawada I, Minami K, Hagiwara R, Ueda S, Yoshiyama T, Kokuto H, Kusumoto T, Oashi A, Miyawaki M, Saito F, Tani T, Ishioka K, Takahashi S, Nakamura M, Ishii M, Sato Y, Fukunaga K. Chronic obstructive pulmonary disease, asthma, and mechanical ventilation are risk factors for dyspnea in patients with long COVID: a Japanese nationwide cohort study. *Respiratory Investigation* 2024; **62**(6): 1094–1101. DOI: [10.1016/j.resinv.2024.09.009](https://doi.org/10.1016/j.resinv.2024.09.009).
- Takaoka H, Kawada I, Hiruma G, Nagashima K, Terai H, Ishida N, Namkoong H, Asakura T, Masaki K, Miyata J, Chubachi S, Ohgino K, Otsuka K, Miyao N, Odani T, Watase M, Baba R, Okamori S, Arai D, Nakachi I, Kuwahara N, Fujiwara A, Okada T, Ishiguro T, Isono T, Ishii M, Sato Y, Fukunaga K. Long COVID among the first three waves of COVID-19 in Japan: a multicentre cohort study. *BMJ Open Respiratory Research* 2024; **11**(1): e002137. DOI: [10.1136/bmjresp-2023-002137](https://doi.org/10.1136/bmjresp-2023-002137).

- 32 Yamaguchi T, Kumagai K, Yagi S, Nomura T, Nagashima K, Watanabe M, Makuuchi R, Kawakami K, Matsushima T, Kadowaki S, Haruta S, Cho H, Kakihara N, Otsuka S, Yamada T, Imai Y, Fukunaga H, Boku N. Efficacy of chemotherapy for patients with gastric cancer with early recurrence during or after adjuvant chemotherapy with S-1 alone: A multicenter retrospective study. *Scientific Reports* 2024; **14**(1): 21854. DOI: [10.1038/s41598-024-72423-x](https://doi.org/10.1038/s41598-024-72423-x).
- 33 Aotsuka Y, Misawa S, Suichi T, Shibuya K, Nakamura K, Kano H, Otani R, Morooka M, Ogushi M, Nagashima K, Sato Y, Kuriyama N, Kuwabara S. Multifocal motor neuropathy in Japan: A nationwide survey on prevalence, clinical profiles, and treatment. *Muscle & Nerve* 2024; **70**(5): 1027–1033. DOI: [10.1002/mus.28251](https://doi.org/10.1002/mus.28251).
- 34 Katsumata Y, Muramoto Y, Ishida N, Takemura R, Nagashima K, Ikoma T, Kawamatsu N, Araki M, Goda A, Okawara H, Sawada T, Ichihara YK, Hattori O, Yamaoka K, Seki Y, Ryuzaki T, Ikura H, Nakashima D, Nagura T, Nakamura M, Sato K, Shiraishi Y. Sweat lactate sensor for detecting anaerobic threshold in heart failure: a prospective clinical trial (LacS-001). *Scientific Reports* 2024; **14**(1): 18985. DOI: [10.1038/s41598-024-70001-9](https://doi.org/10.1038/s41598-024-70001-9).
- 35 Fujita M, Nagashima K, Uno T, Hashimoto H, Suzuki K, Kasai T, Yamaguchi K, Onouchi Y, Sato D, Fujisawa T, Hata A. Impact of the COVID-19 pandemic on hypofractionated radiotherapy use for breast cancer in Japan: a nationwide study. *Advances in Radiation Oncology* 2024; **9**(8): 101555. DOI: [10.1016/j.adro.2024.101555](https://doi.org/10.1016/j.adro.2024.101555).
- 36 Hishikawa A, Nishimura ES, Yoshimoto N, Nakamichi R, Hama EY, Ito W, Maruki T, Nagashima K, Shimizu-Hirota R, Takaishi H, Itoh H, Hayashi K. Predicting exacerbation of renal function by DNA methylation clock and DNA damage of urinary shedding cells: a pilot study. *Scientific Reports* 2024; **14**(1): 11530. DOI: [10.1038/s41598-024-62405-4](https://doi.org/10.1038/s41598-024-62405-4).
- 37 Yoshitake M, Sugiyama A, Shimohata T, Araki N, Suzuki M, Shibuya K, Nagashima K, Hattori N, Kuwabara S. Delivering the diagnosis of multiple system atrophy: A multicenter survey on Japanese neurologists' perspectives. *BMC Neurology* 2024; **24**(1): 160. DOI: [10.1186/s12883-024-03666-4](https://doi.org/10.1186/s12883-024-03666-4).
- 38 Fujita M, Nagashima K, Shimazu M, Suzuki M, Tauchi I, Sakuma M, Yamamoto S, Hanaoka H, Shozu M, Tsuruoka N, Kasai T, Hata A. Effectiveness of self-sampling human papillomavirus test on pre-cancer detection and screening uptake in Japan: The ACCESS randomized controlled trial. *International Journal of Cancer* 2024; **155**(5): 905–915. DOI: [10.1002/ijc.34970](https://doi.org/10.1002/ijc.34970).
- 39 Uchida S, Uno S, Kondo M, Uwamino Y, Namkoong H, Nishimura T, Misawa K, Kashimura S, Yamato K, Ishizaka T, Nagashima K, Kitagawa Y, Hasegawa N. Factors affecting motivation for receiving a booster dose of the COVID-19 vaccine among Japanese university students and staff: A cross-sectional questionnaire survey. *Scientific Reports* 2024; **14**(1): 8009. DOI: [10.1038/s41598-024-58603-9](https://doi.org/10.1038/s41598-024-58603-9).
- 40 Miyazaki N, Iwasaki T, Sakai H, Watanuki R, Tanizawa Y, Cai Z, Kawaguchi T, Tsurutani J, Nagashima K. Risk factors for recurrence in patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative early breast cancer in Japan: a systematic literature review and meta-analysis. *Current Medical Research and Opinion* 2024; **40**(5): 827–837. DOI: [10.1080/03007995.2024.2332436](https://doi.org/10.1080/03007995.2024.2332436).
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- 42 Fujita M, Yamaguchi K, Nagashima K, Suzuki K, Kasai T, Hashimoto H, Onouchi Y, Sato D, Fujisawa T, Hata A. Impact of the COVID-19 pandemic on gastric surgery in Japan: A nationwide study using interrupted time-series analyses. *Journal of Gastroenterology and Hepatology* 2024; **39**(7): 1277–1284. DOI: [10.1111/jgh.16533](https://doi.org/10.1111/jgh.16533).
- 43 Okada M, Ishida N, Kanzaki S, Kawada I, Nagashima K, Terai H, Hiruma G, Namkoong H, Asakura T, Masaki K, Ohgino K, Miyata J, Chubachi S, Kodama N, Maeda S, Sakamoto S, Okamoto M, Nagasaki Y, Umeda A, Miyagawa K, Shimada H, Minami K, Hagiwara R, Ishii M, Sato Y, Fukunaga K. Upper respiratory symptoms as long COVID revealed through a cohort study of patients with COVID-19. *OTO Open* 2024; **8**(1): e120. DOI: [10.1002/oto2.120](https://doi.org/10.1002/oto2.120).

- 44 Tsutsui K, Ukita S, Kondo M, Toshima G, Miyazaki N, Nagashima K, Ohmura M, Tsuchihashi S, Tsuji Y, Katoh M, Aida N, Kobayashi Y, Ohtsu Y, Fujita Y, Tanaka S, Watanabe H, Naruse Y, Iizuka I, Kato H, Mashimo Y, Senbonmatsu T. Synergistic effect of motivation for the elderly and support for going out II; measures to induce elderly men to go out. *Geriatrics* 2024; **9**(1): 21. DOI: [10.3390/geriatrics9010021](https://doi.org/10.3390/geriatrics9010021).
- 45 Okui J\*, Nagashima K\*, Matsuda S\*, Sato Y, Okamura A, Kawakubo H, Muto M, Kakeji Y, Kono K, Takeuchi H, Watanabe M, Doki Y, Bamba T, Fukuda T, Fujiwara H, Sato S, Noma K, Miyata H, Fujita T, Kitagawa Y. Recurrence-free survival as a surrogate endpoint for overall survival after neoadjuvant chemotherapy and surgery for oesophageal squamous cell carcinoma. *British Journal of Surgery* 2024; **111**(2): znae038. DOI: [10.1093/bjs/znae038](https://doi.org/10.1093/bjs/znae038). (\*equally contributed)
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- 47 Yamada Y, Nagashima K, Azuma M, Masutani M, Ichikawa H, Iwasa S, Takahashi N, Hirano H, Kanato K, Machida N, Kinoshita T, Hata H, Kawakami H, Takahari D, Boku N, Kurokawa Y, Terashima M, Yoshikawa T, Sekine S, Hiraoka N. Predictive and prognostic value of excision repair cross-complementing group 1 in patients with advanced gastric cancer. *BJC Reports* 2024; **2**: 18. DOI: [10.1038/s44276-024-00046-w](https://doi.org/10.1038/s44276-024-00046-w).
- 48 Kashiro A, Kobayashi M, Oh T, Miyamoto M, Atsumi J, Nagashima K, Takeuchi K, Nara S, Hijioka S, Morizane C, Kikuchi S, Kato S, Kato K, Ochiai H, Obata D, Shizume Y, Konishi H, Nomura Y, Matsuyama K, Xie C, Wong C, Huang Y, Jung G, Srivastava S, Kutsumi H, Honda K. Clinical development of a blood biomarker using apolipoprotein-A2 isoforms for early detection of pancreatic cancer. *Journal of Gastroenterology* 2024; **59**(3): 263–278. DOI: [10.1007/s00535-023-02072-w](https://doi.org/10.1007/s00535-023-02072-w).
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Hashimoto K, Takashima A, Nagashima K, Okazaki S, Nakajima TE, Kato K, Hamaguchi T, Yamada Y, Shimada Y. Progression-free survival in first-line chemotherapy is a prognostic factor in second-line chemotherapy in patients with advanced gastric cancer. *Journal of Cancer Research and Clinical Oncology* 2010; **136**(7): 1059–1064. DOI: [10.1007/s00432-009-0752-8](https://doi.org/10.1007/s00432-009-0752-8).

## Papers Under Review / Preprints

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### STATISTICAL METHODOLOGY AND APPLICATIONS IN BIOSTATISTICS

1 Nagashima K, Noma H, Furukawa TA. pimeta: an R package of prediction intervals for random-effects meta-analysis. arXiv: [2110.07856](https://arxiv.org/abs/2110.07856).

### MEDICAL RESEARCHES

2 Yuda S, Kato K, Sasaki Y, Takahashi N, Shoji H, Takashima A, Okita N, Honma Y, Iwasa S, Hamaguchi T, Nagashima K, Boku N. Risk factors for FN, mucositis and esophagitis of combination chemotherapy with docetaxel, cisplatin, and 5-fluorouracil for esophageal cancer. DOI: [10.21203/rs.3.rs-62898/v1](https://doi.org/10.21203/rs.3.rs-62898/v1).

## Funding History

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### BIOSTATISTICS

#### **Comprehensive study on the methodology of survival analysis (Grant number: 25K15024)**

*Principal Investigator*

JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE (JSPS) KAKENHI, GRANT-IN-AID FOR SCIENTIFIC RESEARCH (C)

*April 2025–March 2029*

#### **Statistical inference for random-effects meta-analyses under model misspecification (Grant number: 19K20229)**

*Principal Investigator*

JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE (JSPS) KAKENHI, GRANT-IN-AID FOR YOUNG SCIENTISTS

*April 2019–March 2022*

#### **Developments of statistical inference, prediction, and modeling methods for network meta-analysis (Grant number: 19H04074)**

*Co-investigator*

JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE (JSPS) KAKENHI, GRANT-IN-AID FOR SCIENTIFIC RESEARCH (B)

*April 2019–March 2020*

#### **Statistical inference for rare event data and its application in clinical researches (Grant number: 16K16014)**

*Principal Investigator*

JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE (JSPS) KAKENHI, GRANT-IN-AID FOR YOUNG SCIENTISTS (B)

*April 2016–March 2019*

### MEDICAL RESEARCH

#### **Investigation whether the combination of AI in gastric cancer screening using endoscopy can increase the detection rate of gastric cancer and reduce the load of double check system**

*Co-investigator*

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER

CONTROL

*April 2025–March 2028*

**Study of enfortumab vedotin in advanced small intestinal adenocarcinoma refractory or intolerant to platinum-based combination therapy: a phase II single-arm trial**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

*Co-investigator*

*April 2025–March 2028*

**Development of in vitro diagnostics for precision medicine based on subtyping with pre-treatment biopsies of intractable esophageal cancer**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

*Co-investigator*

*October 2024–March 2027*

**Development of blood biomarkers for risk stratification in pancreatic cancer and colorectal cancer**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PROJECT FOR PROMOTION OF CANCER RESEARCH AND THERAPEUTIC EVOLUTION

*Co-investigator*

*April 2024–March 2026*

**Clinical development of blood biomarkers for malignant risk stratification from precancerous pancreatic lesions using estimation of pancreatic exocrine function**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

*Co-investigator*

*April 2024–March 2027*

**Research to promote public awareness for supporting women's physical and mental health toward improving the healthy life expectancy**

THE MINISTRY OF HEALTH LABOUR AND WELFARE, HEALTH LABOUR SCIENCES RESEARCH GRANT

*Co-investigator*

*April 2023–March 2027*

**Development of early detection biomarkers for gastroenterological cancer by antibody-based comprehensive screening**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PROJECT FOR PROMOTION OF CANCER RESEARCH AND THERAPEUTIC EVOLUTION (P-PROMOTE)

*Co-investigator*

*April 2022–March 2024*

**Clinical development of a diagnostic method for early-stage pancreatic cancer and risk factors for pancreatic cancer malignancy using a blood biomarker to evaluate a pancreatic exocrine function**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

*Co-investigator*

*April 2021–March 2024*

**Study for clinical development of precision medicine for esophageal cancer**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PROJECT FOR CANCER RESEARCH AND THERAPEUTIC EVOLUTION (P-CREATE)

*Co-investigator*

*April 2021–March 2023*

**Health literacy improvement of cervical cancer prevention using information and communications technology (Grant number: 19K22737)**

JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE (JSPS) KAKENHI, CHALLENGING RESEARCH (EXPLORATORY)

*Co-investigator*

*July 2019–March 2022*

**Practical application of efficient pancreatic cancer screening with plasma biomarker**

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

*Co-investigator*

*December 2018–March 2020*

**Practical research of blood biomarkers for predicting effects of postoperative adjuvant chemotherapies by metastatic activity analysis of non-small cell lung cancer**

*Co-investigator*

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

*April 2017–March 2020*

**Developing an early-detection and risk-stratification biomarkers for cancer by analyzing post-translational modifications to proteins and peptides**

*Co-investigator*

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PROJECT FOR CANCER RESEARCH AND THERAPEUTIC EVOLUTION (P-CREATE)

*April 2017–March 2022*

**Evaluation study for efficacy and safety of drug therapy based on sex differences**

*Co-investigator*

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PROJECT FOR WHOLE IMPLEMENTATION TO SUPPORT AND ENSURE THE FEMALE LIFE—WISE

*November 2016–March 2019*

**Development of efficient screening method for early detection and risk stratification of pancreatic cancer**

*Co-investigator*

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

*September 2016–March 2017*

## Teaching History

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**Biostatistics and medical informatics**

SCHOOL OF MEDICINE, KEIO UNIVERSITY

*2022–present*

**Public Health II**

SCHOOL OF MEDICINE, KEIO UNIVERSITY

*2022–2023*

**Biostatistics**

GRADUATE SCHOOL OF MEDICINE, KEIO UNIVERSITY

*2021–present*

**Design and analysis of clinical trials**

GRADUATE SCHOOL OF HEALTH MANAGEMENT, KEIO UNIVERSITY

*2019–present*

**Linear statistical inference**

GRADUATE SCHOOL OF ENGINEERING, TOKYO UNIVERSITY OF SCIENCE

*2016–present*

**Introduction of clinical research**

GRADUATE SCHOOL OF MEDICAL AND PHARMACEUTICAL SCIENCES, CHIBA UNIVERSITY

*2014*

**Principles of biostatistics**

GRADUATE SCHOOL OF MEDICAL AND PHARMACEUTICAL SCIENCES, CHIBA UNIVERSITY

*2010–2018*

## Professional Activities

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### PROFESSIONAL AFFILIATIONS

## **American Statistical Association**

MEMBER

2011–present

## **The International Biometric Society**

MEMBER

2008–present

## EDITORIAL ROLE

### **Japanese Journal of Statistics and Data Science**

ASSOCIATE EDITOR

2023–present

[Website](#)

### **Japanese Journal of Biostatistics**

ASSOCIATE EDITOR

2023–present

[Website](#)

## JOURNAL REVIEWER

### **Biostatistics & Statistical Methodology**

Statistics in Medicine

Statistical Methods in Medical Research

Journal of the Royal Statistical Society: Series C (Applied Statistics)

Biometrical Journal

Research Synthesis Methods

Annals of the Institute of Statistical Mathematics

Statistics in Biopharmaceutical Research

Japanese Journal of Statistics and Data Science

Biostatistics & Epidemiology

BMC Medical Research Methodology

Journal of Statistical Computation and Simulation

Statistical Applications in Genetics and Molecular Biology

Contemporary Clinical Trials Communications

Stats

### **Medical Journal**

Nature Communications

European Journal of Epidemiology

BMJ Public Health

Annals of Surgical Oncology

Cancer Science

Esophagus

Diabetes, Obesity and Metabolism

Aging

Expert Review of Respiratory Medicine

Epidemiology and Infection

Sleep Medicine

Trials

PLoS ONE

BMJ Open

Nanomedicine

Cancer Biomarkers

Asia-Pacific Journal of Clinical Oncology

Journal of Clinical Pharmacy and Therapeutics  
International Journal of Environmental Research and Public Health

### Journals in Other Fields

Entropy  
Behaviormetrika  
The Journal of Experimental Education  
Journal of the Royal Society Interface  
Distributed Ledger Technologies  
BMC Bioinformatics  
Mathematics

## Softwares

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<b>gstest Package</b>	<i>Creator</i>
R PACKAGE: GENERALIZED TWO-SAMPLE KOLMOGOROV-SMIRNOV TEST FOR RIGHT-CENSORED DATA	2025
<a href="https://nshi-stat.github.io/gstest/">https://nshi-stat.github.io/gstest/</a>	
<b>surrosurvo Package</b>	<i>Creator</i>
R PACKAGE: EVALUATION OF INDIVIDUAL-LEVEL SURROGACY FOR SURVIVAL AND ORDINAL ENDPOINTS	2024
<a href="https://nshi-stat.github.io/surrosurvo/">https://nshi-stat.github.io/surrosurvo/</a>	
<b>RevGadgets Package</b>	<i>Contributor</i>
R PACKAGE: VISUALIZATION AND POST-PROCESSING OF REVBAYES ANALYSES	2021
<a href="https://cran.r-project.org/package=RevGadgets">https://cran.r-project.org/package=RevGadgets</a>	
<b>%stabcox</b>	<i>Creator</i>
SAS MACRO: A STANDARD SAS MACRO COLLECTION FOR COX REGRESSION	2019
<a href="https://nshi.jp/contents/sas/stab">https://nshi.jp/contents/sas/stab</a> (in Japanese)	
<b>%stab</b>	<i>Creator</i>
SAS MACRO: A STANDARD SAS MACRO COLLECTION FOR TABLE 1	2018
<a href="https://nshi.jp/contents/sas/stab">https://nshi.jp/contents/sas/stab</a> (in Japanese)	
<b>pimeta Package</b>	<i>Creator</i>
R PACKAGE: PREDICTION INTERVAL FOR RANDOM-EFFECTS META-ANALYSIS; CRAN TASK VIEW: METAANALYSIS	2017
<a href="https://cran.r-project.org/package=pimeta">https://cran.r-project.org/package=pimeta</a>	
<b>ph2bayes Package</b>	<i>Creator</i>
R PACKAGE: BAYESIAN SINGLE-ARM PHASE II DESIGNS; CRAN TASK VIEW: EXPERIMENTALDESIGN	2016
<a href="https://cran.r-project.org/package=ph2bayes">https://cran.r-project.org/package=ph2bayes</a>	
<b>%skmdata</b>	<i>Creator</i>
SAS MACRO: A SAS MACRO FOR THE KAPLAN-MEIER PLOT WITH SGPLOT PROCEDURE	2015
<a href="https://github.com/nshi-stat/skmdata">https://github.com/nshi-stat/skmdata</a>	
<b>RcmdrPlugin.KMggplot2 Package</b>	<i>Creator</i>
R PACKAGE: GG PLOT2 GUI FRONTEND, R COMMANDER PLUG-IN FOR DATA VISUALIZATION WITH 'GGPLOT2'	2012
<a href="https://cran.r-project.org/package=RcmdrPlugin.KMggplot2">https://cran.r-project.org/package=RcmdrPlugin.KMggplot2</a>	
<b>mmcm Package</b>	<i>Creator</i>
R PACKAGE: MODIFIED MAXIMUM CONTRAST METHOD (NAGASHIMA K, ET AL. SAGMB 2011)	2009
<a href="https://cran.r-project.org/package=mmcm">https://cran.r-project.org/package=mmcm</a>	